REMARKS

In the Office Action, Claims 27-34 and 78-107 were either rejected under 35 U.S.C. § 112 and 35 U.S.C. § 103. In this Amendment, Claims 27, 82, 93, and 104 have been amended, Claims 108-112 have been added, and Claims 32, 87, 92, and 99-101 have been canceled. Claims 27-31, 33-34 and 78-112 remain pending for further consideration.

Rejections Under 35 U.S.C. § 112

Claims 27-34 and 78-107 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that the "originally filed application does not support the amendment 'the free end is proximal of the fixed end' the examiner believes this should be 'the free end is distal of the fixed end.'" Office Action at 2. Applicant does not disagree with the Examiner's suggested claim language, and notes that the current claim language is fully supported. For example, Applicant refers to Figure 7 and 8, reproduced below.

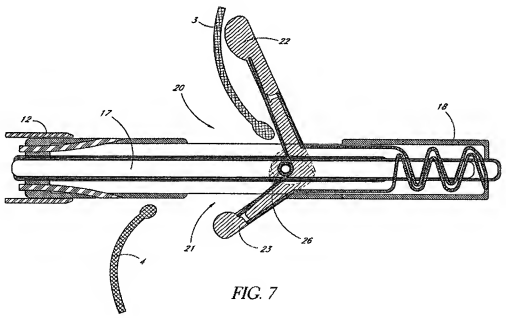

FIG. 7

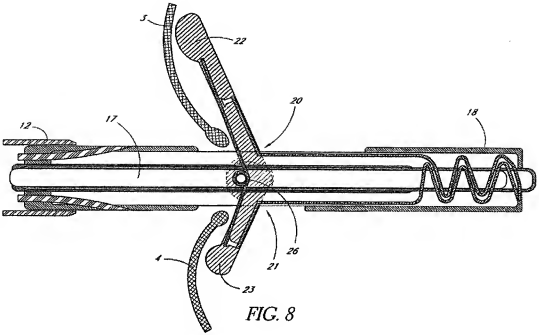

FIG. 8

The publication of the present application recites in Paragraph [0049]:

The Housing Catheter 18 also contains holes within its walls for the extension of fixation devices 24 and 25 from the VIC 19. The VIC 19 is a catheter with a central lumen for a guide wire, is made of material flexible and torqueable, and has a semi-rigid portion that contains the leaflet immobilization apparatus, which consists of the leaflet immobilization supports 22, 23, the spring hinge 26, and the fixation devices 24, 25.

The application's publication at Paragraph [0054] describes:

FIGS. 7 and 8 sequentially depict one embodiment of the present invention showing the independent deployment of posterior [leaflet immobilization supports ("LIS")] 23. Once the anterior LIS 22 extends through the anterior portal 20, the operator may further pull [valve immobilization catheter ("VIC")] VIC 19 *in a proximal direction.* This movement will cause the posterior LIS 23 to move from the lumen of the catheter to the opening of the posterior portal 21. The posterior LIS 23 may be shorter than the anterior LIS 22 taking into account the size difference of the anterior 3 and posterior 4 mitral valve leaflets. Similar to the independent deployment of anterior LIS 22, posterior LIS 23 gradually and independently springs to an open position as the operator pulls the VIC 19 proximally. . . . In FIG. 7, the posterior LIS 23 is shown in a partially extended position shortly after clearing the lumen of the Housing Catheter 18 through the posterior portal 21. Similar to anterior LIS 22 positioning, the posterior LIS 23 is positioned at the ventricular side of posterior leaflet 4. In FIG. 8, posterior LIS 23 is in a fully deployed position and is optimally positioned under posterior leaflet 4. . . .

These passages in the specification describe that the proximal ends of the leaflet immobilization supports 22, 23 are able to move through an arc through the portals 20, 21, while

the distal ends thereof are can be fixed by the hinge 26. (In these figures, the "proximal" end or direction is toward the left side of the page.)

Thus, the specification does support the amendment that "the free end is proximal of the fixed end" as recited in the claims rejected under §112. Applicant requests that the rejection of Claims 27-34 and 78-107 under §112 be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 27-29, 31-34, 78-84, 86-91, 102, and 103 were rejected in the Office Action under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,136,010 to Modesitt et al. (Modesitt) in view of U.S. Patent No. 6,165,183 to Kuehn et al. (Kuehn). Applicant disagrees with and traverses this rejection, but has made certain amendments consistent with the Interview summarized above to expedite allowance. In particular, Claim 27 is now directed to a catheter for accessing the heart and engaging a heart valve that comprises:

> an elongate flexible body, having a proximal end and a distal end, the elongate flexible body having housed therein a fastening material configured to suture two heart leaflets together;
> an anchor zone on a distal portion of the flexible body;
> a first tissue manipulator and a second tissue manipulator carried by the flexible body proximally of the anchor zone, ***the tissue manipulators being movable independently of each other*** and having a fixed end and a free end, the free ends being moveable to an extended position in which the free ends are proximal of the fixed ends, the tissue manipulators being disposed at an angle not more than 90 degrees with respect to the elongate flexible body when in the extended position;
> a first receptacle located within the first tissue manipulator for receiving a first fixating member;
> a second receptacle located within the second tissue manipulator for receiving a second fixating member; and
> a first end of a fastening material disposed within the first receptacle and a second end of the fastening material is disposed within the second receptacle;
> wherein the distal portion is configured to extend at least into an anatomical region adjoining the heart valve and the anchor zone is configured to orient and anchor the catheter so that the at least one tissue manipulator can be positioned at the valve.

These limitations differ from Modesitt. In contrast, Modesitt is directed to a vessel closure device 10 for closing vessel wall punctures. Figures 1 and 12A-12B show that the device 10 includes an articulatable foot 24 near a distal end 16 of a shaft 12 that is inserted through a vessel penetration and actuated so that the foot 24 extends along an axis of the vessel (i.e., a luminal axis).

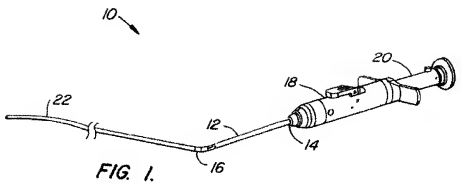

FIG. 1.

The guidebody 22 enables the device 10 to be advanced over a guidewire into the vessel through a vessel puncture and aligns a distal portion of the device 10 with the axis of vessel. The Examiner refers to Figures 12A and 12B as to the operation of the foot 24. In connection with Figure 13E, the Examiner asserts that two ends of the same foot are first and second tissue manipulators.

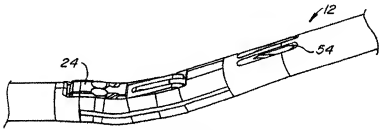

FIG. 12A.

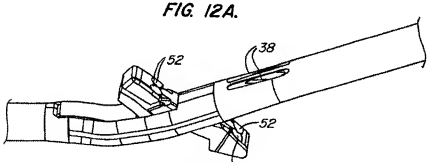

FIG. 12B.

Although Applicant disagrees with this assertion, certain amendments have been made to Claim 27 to expedite allowance. Modesitt does not teach or suggest, for example, "a first tissue manipulator and a second tissue manipulator carried by [a] flexible body proximally of [an] anchor zone, the tissue manipulators being ***movable independently of each other***" as now recited in Claim 27. Rather, the foot 24 is illustrated and described as being deployed at by a

combination of sliding axially along the shaft 12, e.g., from the position of Figure 12A, and pivoting out from the shaft, e.g., to the position in Figure 12B.

The Examiner further states in the Office Action at P. 5:

> Modesitt teaches the claimed invention as described above but is silent regarding the material choice for the shaft, 12. However Cribier teaches an interventional catheter for accessing the heart wherein elongate body if flexible (Fig. 8) and is configured to bend in order to access the heart and bend through the arteries. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Modesitt with flexible body of Cribier in order to access a wide variety of medical problems that require passage through tortuous pathways in the body.

These assertions regarding Cribier do not address the shortcomings of Modesitt in view of the amendments to Claim 27. Also, although the Examiner makes reference to Kuehn, there is no specific application of this reference to Claim 27. However, Applicant notes that Kuehn does not teach or suggest, *inter atlia,* in connection with a catheter for accessing the heart:

> a first receptacle located within the first tissue manipulator for receiving a first fixating member;
> a second receptacle located within the second tissue manipulator for receiving a second fixating member; and
> a first end of a fastening material disposed within the first receptacle and a second end of the fastening material is disposed within the second receptacle. . .

For at least the above reasons, Claim 27 is allowable over the cited art.

Claims 28-31, 33-34, 78-81, 97-98, and 107 depend from Claim 27 and further define the invention thereof. As discussed above, amended Claim 27 is not obvious in view of the cited art. Accordingly, for at least the same reasons as stated above in connection with Claim 27, Claims 28-31, 33-34, 78-81, 97-98, and 107 are not obvious in view of the cited art. Applicants respectfully request that the rejection of Claims 28-31, 33-34, 78-81, 97-98, and 107 based on Modesitt be withdrawn.

Similarly, Claim 82 has been amended to recite a catheter for performing a procedure on the heart, comprising:

> an elongate flexible body, having a proximal end, a distal end and a length sufficient to reach the heart from a femoral vein access;
> ***a first tissue manipulator, a second tissue manipulator, and a hinge coupled with the elongate, flexible body and with at least one of the first and second tissue manipulators for***

pivoting at least one of the first and second tissue manipulators away from the elongate body; and

an elongate, flexible distal portion comprising an anchor zone, the distal portion extending distally of the tissue manipulator;

a fastening material adapted for use in suturing two leaflets of a heart, the fastening material being housed within the distal portion;

wherein the distal portion is sufficiently flexible and long that it can extend through the mitral valve and into the left ventricular outflow tract and the anchor zone is configured to orient and anchor the catheter while the tissue manipulator is positioned at a leaflet of the mitral valve.

For reasons similar to those discussed above, this combination of limitations is not taught or suggested by the applied references. Claims 83-86 and 88-91 depend from Claim 82 and further define the invention thereof. Accordingly, for the reasons stated above, Claims 82-86 and 88-91 are not obvious in view of the cited art. Applicants respectfully request that the rejection of Claims 82-86 and 88-91 based on Modesitt be withdrawn.

New Claims

Claims 108-112 have been added pursuant to the Interview summarized above. Applicant asserts that these claims are fully supported and are allowable over the cited art for the reasons discussed at the Interview.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Andrew M. Douglas at (949) 721-7623 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 15, 2009

By: 

Andrew M. Douglas
Registration No. 51,212
Attorney of Record
Customer No. 20,995
(949) 760-0404

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